

## **REMARKS**

### **I. Preliminary Remarks**

With this response, Applicant amends claim 26 by clarifying that one of the elements of the instant invention is “total genomic DNA isolated from the tumor cells of said animal”. With this response Applicant also submits new claim 54 dependent on claim 26 and directed to a method of treating tumors utilizing “sheared total genomic DNA isolated from the tumor cells of said animal.” Neither amendment of claim 26 nor submission of new claim 54 introduces any new matter. The amendment of claim 26 and a newly filed claim 54 are fully supported by the instant specification and specifically by pages 30 to 32 of the instant specification.

### **II. Patentability Arguments**

#### **A. The Rejections Under 35 U.S.C. § 102 (b) and (e) Should Be Withdrawn**

The Examiner maintained the rejection of claims 26, 41, 42, 44-45 under 35 USC § 102(b) as being anticipated by EP 0569 678 A2 to Eisenbach *et al* (Eisenbach 1), alleging at paragraph 3 on page 2 of the Final Office Action that,

the term “genomic DNA” as recited in the instantly claimed invention has not been adequately defined in the specification, therefore because the MHC determinants used by Eisenbach *et al.* were derived from the genome of a tumor cell of a mouse, hence “genomic DNA,” one of skill in the art would have anticipated that the limitation of transfecting an antigen presenting cell with a genomic DNA was also encompassed within the scope of the claims, wherein the genomic DNA used Eisenbach *et al.* was the DNA encoding the MHC determinant being transfected into the cell.

Applicant respectfully submits that the term “genomic DNA” is clearly defined in the specification. However, in order to expedite the prosecution of the instant specification, Applicant amends claim 26 to recite “total genomic DNA isolated from the tumor cells of said animal.”

Applicant directs the Examiner to pages 30 to 32 of the instant specification as filed, wherein Applicant teaches in detail how an artisan practicing the invention can isolate the total genomic DNA from different types of tumor cells of a subject in need of anti-cancer treatment. Thus, Applicant respectfully submits to the Examiner that the instant specification fully defines the element “total genomic DNA isolated from the tumor cells of said animal” and teaches how to make and use the element.

In contrast to the instant invention, Eisenbach 1 does not teach the use of “total genomic DNA isolated from the tumor cells of said animal” or “sheared total genomic DNA” isolated from the tumor cells of said animal, as recited by the present claims. Instead of the total genomic DNA isolated from the tumor cells of said animal, Eisenbach 1 (in lines 17-21 of page 4) teaches that “a malignant tumor maybe vaccinated with tumor cells transfected with MHC genes . . . The MHC genes may be cloned from cells or tissues . . .” Thus, Eisenbach 1 teaches vaccines made of tumor cells transfected with cloned MHC genes and not with total genomic DNA (i.e. uncloned) as instantly claimed.

Since Eisenbach 1 does not teach transfection with “total genomic DNA isolated from the tumor cells of said animal,” Eisenbach 1 cannot properly anticipate the present invention, and therefore the rejection should be withdrawn.

The Examiner also maintained the rejection of claims 26, 41, 42, 44-45 under 35 USC § 102(e) as being anticipated by U.S. Patent 5,750,102 to Eisenbach *et al.* (Eisenbach 2) essentially for the same reasons as he provided for Eisenbach 1 reference. As discussed above, the instant claims recite “total genomic DNA isolated from the tumor cells of said animal.” Eisenbach 2 does not teach transfection with “total genomic DNA isolated from the tumor cells of said animal.” Therefore, Eisenbach 2 cannot anticipate the present invention and thus the rejections may properly be withdrawn.

B. The Rejections Under 35 U.S.C. § 112, First Paragraph, Should Be Withdrawn

In line 7 of the Continuation Sheet of the Advisory Notice, the Examiner alleges that “the specification does not provide enabling disclosure concerning the prevention of a tumor” and maintains his rejection to claims 47-53 under 35 U.S.C. § 112, first paragraph. In line 11 of the Continuation Sheet, the Examiner alleges that it is not possible to identify which members within that population would require administration.

Applicant directs attention of the Examiner to the fact that claims 47-53 do not claim prevention of tumor but rather “preventing of tumor recurrence.”

Webster’s “New World Dictionary” defines recurrence as an act of repetition or return (Exhibit A). Thus, a person of ordinary skill would understand from reading Applicant’s claims 47-53 that claims 47-53 are directed to a class of animals who had tumors in the past, were treated for their tumors using the vaccines of the present invention which in turn provided them with at least partial immunity to the tumors.

Applicant submits that the instant specification fully enables claims 47-53 as demonstrated, for example, in Example 15 at pages 72-74 of the specification.

In that Example, surviving mice who had previously been injected with both breast tumor cells and a breast cancer vaccine prepared according to the methods of the present invention were challenged with a second injection of breast cancer cells. Naïve mice (mice who had not been exposed to either the vaccine or the breast tumor cells) were also injected with breast cancer cells with no vaccine and both groups were monitored for survival. The mean survival time of those mice who were previously vaccinated, was significantly higher than that of mice who had not previously

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received the vaccine ( $P < .02$ ) suggesting that the previously treated mice had developed at least partial immunity against subsequent tumor challenge.

The Examiner admits himself at lines 11 and 12 of the Advisory Notice that “in the Example [15] cited by the applicant, the tumor was already present and therefore the population was already defined before the administration of the composition.” This is exactly the case. Applicant claims “a method of preventing of tumor recurrence” in a defined population of animals which had tumors in the past and who were treated for their tumors using the vaccines of the present invention which has been shown to inhibit recurrence of their tumors.

In view of the foregoing, Applicant submits that claims 47-53 are enabled and therefore requests that the rejection of claims 47-53 under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

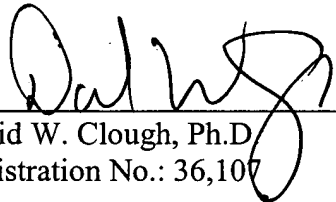
### Conclusion

Applicant respectfully submits that the amended claims are in condition for allowance and early notification thereof is requested. Applicant requests a telephone interview with the Examiner to discuss the amendments submitted with this response. If in the interest of expediting prosecution, the Examiner has questions or comments he is invited to telephone the undersigned at the indicated telephone number.

Respectfully submitted,

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